Licence Renewal Inspection Report for Treatment and Storage Centres

NURTURE
Nottingham University Research and Treatment Unit in Reproduction
0076

Date of Inspection: 18 October 2006
Date of Licence Committee: 18 January 2007

TRIM: 06/3144

CENTRE DETAILS

Centre Address	'B' Floor, East Block, University Hospital Nottingham, NG7 2UH United Kingdom
Telephone Number	0115 8230700
Type of Inspection	Renewal
Person Responsible	James Hopkisson
Nominal Licensee	Ian Johnson
Licence Number	L0076/11/a
Inspector(s)	Debra Bloor
	Delia Kelleher
	Janet Kirkland
	Lydia Harley (HFEA observer)
Fee Paid - date	Not at 3 January 2007. Invoice due for payment by 12 January 2007.
Licence expiry date	28 February 2007

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About the Inspection:
This inspection visit was carried out on 18 October 2006 and lasted for 6 hours. The report covers the pre-inspection analysis, the visit and information received between 5 October 2005 and 18 October 2006.

The purpose of the inspection is to ensure that centres are providing a quality service for patients in compliance with the HF&E Act 1990, Code of Practice and to ensure that centres are working towards compliance with the EU Tissue and Cells Directive 2004/23/EC. Inspections are always carried out when a licence is due for renewal although other visits can be made in between.

The report summarises the findings of the licence renewal inspection highlighting areas of good practice, as well as areas where further improvement is required to improve patient services and meet regulatory requirements. It is primarily written for the Licence Committee who make the decision about the centre's licence renewal application. The report is also available to patients and the public following the Licence Committee meeting.

At the visit the inspection team assesses the effectiveness of the centre through five topics. These are:
How well the centre is organised
The quality of the service for patients and donors
The premises and equipment
Information provided to patients and to the HFEA
The clinical and laboratory processes and competence of staff.

An evaluation is given at the end of each topic and for the overall effectiveness of the centre:
No Improvements Required – given to centres where there are no Code of Practice, legal requirements, recommendations or conditions that need to be imposed.
Some Improvements Required – given to centres that are generally satisfactory but with areas that need attention. Recommendations will usually be made to help Persons Responsible to improve the service.
Significant Improvements Required – given to centres that have considerable scope for improvement and have unacceptable outcomes in at least one area, causing concern sufficient to necessitate an immediate action plan or conditions put on the Licence.

The report includes a response form for the Person Responsible to complete following the inspection.

The HFEA welcomes comments from patients and donors, past and present, on the quality of the service received. A questionnaire for patients can be found on the HFEA website www.hfea.gov.uk .

Brief Description of the Centre and Person Responsible

The centre provides self funded and NHS funded treatments to patients from the local area. NURTURE is owned by the University of Nottingham and is housed in the Queens Medical Centre at the University Hospital, Nottingham. The centre registered with the Healthcare Commission in 2005.

NURTURE provided 332 cycles of IVF and ICSI treatment for 276 patients in the time period from 01/07/05 to 30/06/06. The centre also provided 10 cycles of IVF with egg sharing with 9 cycles of treatment to egg share recipients and 4 cycles of altruistic egg donation with 3 cycles of treatment provided to egg recipients. This represents a 12% increase in workload from the previous year. Over the same time period, the centre reported a 45% twin birth rate with no higher order pregnancies. The centre also provided 15 cycles of DI treatment for 10 patients. This represents a decrease in provision from 18 cycles in the previous year.

The Person Responsible (PR) has been in post since September 2003 and is appropriately qualified and experienced for the role.

Activities of the Centre (data extracted from HFEA register for time period 01/07/05 to 30/06/06

Licensed treatment cycles	332 (IVF, ICSI and FET)	
Donor Insemination	15	
Unlicensed treatments	Intrauterine insemination (IUI) Timed intercourse Ovulation induction Infertility Investigations	
Research	Yes	
Storage	Yes	

Summary for Licence Committee

An analysis of HFEA register information of treatment outcomes for the period from March 2002 to April 2005 shows that live birth rates reported by the centre for IVF and ICSI, frozen embryo replacement and DI treatments were in line with national average figures. However non validated data extracted from the HFEA register for the more recent period from July 2005 to June 2006 showed an increase in live birth rates.

The centre has complied with all of the recommendations of the 2005 interim report. A number of issues were identified and discussed on the day of the inspection and the recommendations related to these issues are summarised below. The improvements required are minor and the inspection team would support the renewal of the centres licence.

Risk Assessment

Centre's risk status 15% - low

Overall judgement of the effectiveness of the centre

No Improvements required	Some Improvement required	Significant Improvement required
	✓	

Evaluations from the inspection

Topic	No Improvements required	Some Improvement required	Significant Improvement required
1. Organisation		✓	
2. Quality of the service	✓		
3. Premises and Equipment	✓		
4. Information		✓	
5. Laboratory and clinical processes		✓	

Breaches of the Act or Code of Practice

Breach	Action required	Time scale
At the time of the inspection, the centre had embryos in store for which there was no valid consent to storage (storage expired 25 June 2006).	The HFEA has been kept fully informed of the issue and the centre reported that they will continue their efforts to resolve the issue as soon as possible.	HFEA to be advised when issue resolved
The centre carried out a three embryo transfer in a patient aged less than 40 years. The rationale behind the decision to carry out the transfer was clearly documented.	None	N/A

Non-Compliance

None identified

Recommendations	Time scale
The PR should consider formalising contingency arrangements.	Not specified
The centre should consider assessing all activities which give rise to risk prospectively.	Not specified
The centre should assess whether there is any risk associated with the checking systems currently in place for resuscitation equipment.	Within 3 months
The PR should develop a system for monitoring the content of patient information and for implementing changes as required.	Within 3 months
The centre should develop a training programme to ensure that all staff participate in mandatory training and BLS training (where appropriate) in the next year.	Within 3 months

Proposed licence variations

None

Changes/ improvements since last inspection

Recommendation	Action taken
Information for patients receiving treatment with donor gametes required updating as a matter of urgency;	Changes implemented as evidenced by submission of revised documentation.
Centre should ensure that all staff receive appropriate training and that a record of training is maintained;	Staff interviewed were able to demonstrate participation in training, including life support training. Not all staff were able to provide evidence of participation in mandatory health and safety training.
The centre should consider formalising and documenting the audit of outcomes;	Although there is no formal programme of audit, in the course of discussion it was reported that an active programme of audit is undertaken and meeting agendas showed that time is allocated to the review of outcomes.
The centre should review the security of the cryostore;	It was reported that issues relating to the security of the cryostore are being resolved.

Additional licence conditions and actions taken by centre since last inspection

None

Report of Inspection findings

1. **Organisation**

Desired Outcome: The centre is well-organised and managed and complies with the requirements of the HFE Act.

Summary of findings from inspection
Evidence is drawn from:

- Leadership and management
- Organisation of the centre
- Risk management
- Incident management
- Contingency arrangements
- Clinical governance
- Payment of treatment fees

Areas of firm compliance
The PR has implemented changes as recommended in the report of the previous inspection. The centre has systems in place for clinical governance and quality management and attained International Standardization Organization (ISO 9001) accreditation in 2006. The centre also registered with the Health Care Commission In 2005. The centre has a written adverse incidents policy and incidents have been reported to the HFEA within prescribed timeframes. Learning from incidents has been clearly demonstrated. In the course of the inspection staff were able to demonstrate awareness of recent HFEA Alerts and the system for ensuring that unit staff are made aware of HFEA Alerts was observed. Documentation submitted to the HFEA showed evidence of version control and periodic review. The centre has submitted only 1% of their forms late in the time period from March 2005 to present. The last operational audit was carried out in May 2004 and concluded that there was little evidence of late reporting of treatments by the clinic to the HFEA in the year 2003-4 and no failure to report treatments. Although there is no planned clinical audit programme, the PR reported that aspects of the centres practice are audited as issues are identified. An example was described when anomalies were observed in patient records of welfare of the child (WOC) assessment and a full audit was implemented in response. Evidence of consideration of audit of outcomes was seen in meeting agendas.
Areas for improvement
At the time of the inspection the centre had one outstanding invoice which has exceeded HFEA payment terms of 28 days.

The PR reported that he considers the clinical cover for the unit to be adequate although both the PR and nurse coordinator commented that the nursing team could benefit from additional staff. Unexpected absences in all departments can be accommodated by existing staff: the absence of a member of the embryology team has been successfully accommodated without impact on outcomes or training and support of more junior members of the team. However, there are no formal contingency arrangements in place and it was recommended that the PR consider formalising contingency plans. In relation to concerns relating to workload, the PR should also continue to monitor workload pressures, particularly in the nursing team.

Staff reported that risk assessments have not been carried out prospectively. The centre should consider assessing all activities which give rise to risk prospectively.

Executive recommendations for Licence Committee
None

Areas not covered on this inspection
Resource management Business planning

Evaluation
Some minor improvements required

2. Quality of service

Desired Outcome: Patients receive a good standard of service, appropriate treatment and are treated with courtesy and respect.

Summary of findings from inspection:

- Live birth rates
- 'Welfare of the Child' arrangements
- Confidentiality (including safe storage of patients' records)
- Privacy and dignity of patients
- Complaint handling
- Patient feedback and satisfaction
- Counselling facilities and services
- Donor selection

Live Birth Rates

Analysis of HFEA held register data for the time period March 2002 to April 2005 showed that the centres success rates did not differ significantly from national averages over this time period.

Non validated data extracted from the HFEA register for the time period 01/07/05 to 30/06/06 are as follows:

Outcomes:

	IVF	FET after IVF	ICSI	FET after ICSI	DI
Clinical pregnancy rate per treatment cycle 01/07/05 to 31/06/06	45%	25%	40%	20% Plus 32% for non specified FET	27%
Live birth rate per treatment cycle 01/07/04 to 30/06/05	28%	19%	33%	21%	6%

Although it should be noted that these data compare clinical pregnancy rates with live birth rates, they do suggest that success rates have improved in 2005-6.

Areas of firm compliance

Inspection of patient records showed evidence of the completion of appropriate WOC assessment. Patient information explains the process to patients and the centre reports having a written protocol for the procedure. During discussions staff confirmed that they have an opportunity to contribute to discussions relating to the WOC assessment.

Records are stored in filing cabinets in an area accessible by licensed personnel only and computers in the unit were observed to be password protected. In feedback to the HFEA from 50 patients a single patient commented negatively that discussions held in the recovery room could be overheard by other patients. This was raised in the course of the inspection and staff were aware of the issue. They reported that every effort is made to admit patients to the two

recovery bays alternately to provide the best opportunity for privacy and that discussions are conducted in the area only when absolutely necessary. The inspection team were satisfied that the centre makes every effort to ensure patient privacy and confidentiality.

The centres complaints log was reviewed in the course of the inspection. The log showed that the centre had responded to complaints in line with locally set timescales.

Since the last inspection, 50 patients who have received treatment at the centre have provided feedback to the HFEA. Responses were overwhelmingly positive with 41 respondents having compliments about the treatment they received and only 4 having any complaints. This represents a response rate of around 16% as the centre treated an estimated 312 patients in the reported time period.

Two patients currently receiving treatment at the centre agreed to meet with a member of the inspection team. Both reported satisfaction with the care that they are receiving.

A counselling service is provided by two independent counsellors. Patients can be seen by a counsellor within two weeks of requesting an appointment. Counselling records are kept separately from treatment records. Patients cannot book an appointment with a counsellor directly but members of the administration team have access to the counsellor's appointments diary. Of the 91 patients that have provided feedback to the HFEA over the last three years, 66 patients considered the counselling service accessible and 25 (27%) did not consider the counselling service accessible. Nationally, 31% of patients report that counselling is inaccessible and the inspection team were satisfied with the centres efforts to promote counselling and to make the service accessible.

Inspection of a sample of patient records showed evidence that donor selection and screening is carried out in accordance with requirements.

Areas for improvement
It was recommended that password protection to computers in the embryology office be subject to a "time out" so that if a member of staff is called away before logging off the computer would become locked after a short time.
Executive recommendations for Licence Committee
None
Areas not covered on this inspection
Protection of children arrangements (for patients under 18yrs) Choice of treatments Egg sharing and surrogacy
Evaluation
No improvements required

3. Premises and Equipment

Desired outcome: The premises and equipment are safe, secure and suitable for their purpose.

Summary of findings from inspection:

- Suitable premises
- Storage facilities for embryos and gametes
- Safe equipment, servicing and maintenance
- Prevention of incidents/ accidents

Areas of firm compliance
The premises appeared fit for purpose. Dewars are stored in a designated area which is accessed by licensed personnel and research personnel acting under the direction of the PR. Dewars are individually locked and are fitted with low nitrogen level alarms. There is a suitable system in place for responding to an alarm. The cryostore is fitted with a low oxygen level alarm and there are also procedures in place for responding to the alarm. The centre has a robust system for identifying the expiry of consent to storage of cryopreserved material. At the time of the inspection the centre was storing embryos for which there was no valid consent. The HFEA had been made aware of the circumstances and evidence of considerable ongoing communications with the patients (who do not wish the embryos to be allowed to perish and are exploring how storage could be extended) was shown to a member of the inspection team. The inspector was satisfied that every effort was being made to resolve the issue. The centre should advise the HFEA when the fate of the embryos is decided. The centre has a back up generator to secure the ongoing function of equipment in the event of a power failure. Evidence of the maintenance of a sample of key pieces of laboratory equipment was made available to the inspection team. Emergency resuscitation equipment is available in the unit. The equipment is checked on days when a general anaesthetic is administered. Guidelines[1] state that the responsibility for checking resuscitation equipment rests with the department where the equipment is held and checking should be audited regularly. The frequency of checking will depend upon local circumstances but should ideally be daily. The centre should assess whether there is any risk associated with the checking systems currently in place. Staff reported that if a patient required resuscitation, this would be provided by the specialist team from the Queen Medical Centre. Evidence that HFEA Alerts are communicated to all staff was seen in the course of the inspection.

[1] Cardiopulmonary Resuscitation Standards For Clinical Practice And Training, A Joint Statement from The Royal College of Anaesthetists, The Royal College of Physicians of London,The Intensive Care Society, The Resuscitation Council (UK), October 2004

The centre has a written adverse incidents policy. Incidents are logged and reported to the HFEA as required and appropriate learning from incidents has been demonstrated. The PR was aware of the latest incident reported to the HFEA and of actions taken as a result.

At the time of the last inspection the PR reported difficulty in implementing clinical governance procedures. These issues have now been resolved and the centre has a system in place for communicating governance issues.

Areas for improvement
None
Executive recommendations for Licence Committee
None
Areas not covered on this inspection
None
Evaluation
No improvement required

4. Information

Desired outcome: Information is relevant, clear and up to date for patients and the HFEA

Summary of findings from inspection:

- Information to patients and donors
- Information to the HFEA registry and updates
- Consent
- Information management

Outcome of audit of records
Ten sets of patient records were reviewed in the course of the inspection. All records showed evidence of welfare of the child assessment and consent forms were correct and compatible with treatment.
Areas of firm compliance
The audit of records showed that all required consents were obtained prior to the provision of treatment. Only 1% of their chargeable treatment and outcome forms were submitted to the HFEA late for the time period from March 2005. Documentation submitted to the HFEA showed evidence of version control and most showed evidence of revision. Although written patient information does not cover all of the requirements of the 6th Code of Practice (COP) the PR confirmed that information omitted from the written information is provided verbally to patients. A check sheet recording what information has been provided to patients is included in patient records.
Areas for improvement
The report of the interim inspection in 2005 recommended a number of revisions to patient information. The changes were implemented but not within the anticipated timescales. The PR should ensure that there is a robust system in place for monitoring the content of patient information and for revising information as required.
Executive recommendations for Licence Committee
None
Areas not covered on this inspection
Record keeping Protocols

Evaluation
Some improvement required

5. Laboratory and Clinical Practice

Desired outcome: Staff are competent and recruited in sufficient numbers to ensure safe clinical and laboratory practice.

Summary of findings from inspection:

- Procedures in practice
- Laboratory processes and practice
- Clinical practice
- Staff competence, qualifications, training and CPD

Full time equivalent staff

GMC registered doctors	3 plus one other who works two afternoons
NMC registered nurses	3.5
HPC registered scientists	2
Scientists working towards registration	2 (one member of the team currently on maternity leave)
Support staff (receptionists, record managers, quality and risk managers etc)	4 at time of inspection. New secretary starting in January 2007

Summary of laboratory audit
A full audit of cryopreserved embryos and sperm was carried out in July 2006. No discrepancies were found but a straw containing one embryo was broken in the course of the audit. Patients were informed of the loss and the incident was reported to the HFEA.
Summary of spot check of stored material
Two embryo and two sperm samples were tracked from record to dewar and one sperm and one embryo sample were tracked from dewar to record. No discrepancies were observed.
Areas of firm compliance
Witnessing procedures at the time of egg collection and sperm preparation were observed to be fully compliant with requirements. The centre has a written protocol outlining the requirements for embryo transfer and the circumstances under which a three embryo transfer will be considered. The documents suggest that single embryo transfers are encouraged when appropriate and that three embryo transfer will only be considered in circumstance where there are clinical indications in addition to age. In the pre inspection questionnaire, the PR reported performing a three embryo transfer in a patient aged less than 40 years. The three embryo transfer log showed evidence that the transfer was done after full consideration of the clinical circumstances of the case. All members of the embryology team are registered with the Health Professions Council with the exception of the consultant embryologist, who has applied for registration under the grand parenting scheme and the most recently appointed member of the team, who is completing the Association of Clinical Embryology (ACE) certificate prior to registration. A recently appointed member of the embryology team was able to provide evidence of her participation in the ACE training programme. She was also able to provide evidence of participation in some mandatory health and safety training which was undertaken while employed by the

university.

It was reported that all members of the nursing team are registered with the Nursing and Midwifery Council (NMC) with the exception of auxiliary nurses. The nurse matron reported that members of the nursing team participated in continued professional development (CPD) in the last year and that basic life support (BLS) is undertaken annually by all members of the team.

A recently appointed member of the nursing team reported receiving appropriate induction training and having her competency assessed prior to being allowed to perform tasks unsupervised.

A member of the counselling team reported that both counsellors are members of the British Association of Counselling and Psychotherapy and that she is also a member of the British Infertility Counselling Association. The counsellor reported that she had an opportunity to participate in training and CPD in the last year and that she receives 2 ½ hours of supervision per month.

Members of the clinical team are registered with the General Medical Council and the PR (who has overall responsibility for clinical activity) is on the obstetrics and gynaecology and reproductive medicine specialist registers. A recently appointed member of the clinical team was able to provide evidence of participation in an appropriate induction programme which showed evidence of assessment of competency. He was also able to provide evidence of participation in life support training and CPD in the last year.

Areas for improvement

The documentation of witnessing steps was reviewed in five sets of patient records. Patient records showed evidence of witnessing at all key stages except that undertaken when the male partner provides a sperm sample. This was discussed with a member of the embryology team and it was agreed that the verification of the patients name and cross checking of the information on the sperm pot against records would be documented in records in future.

The most recently appointed member of the nursing team did not undertake BLS training in the last year. Not all staff were able to provide evidence of participation in all mandatory health and safety training in the last year. The centre should develop a training programme to ensure that all staff participate in mandatory training and BLS training (where appropriate) in the next year.

There is a written induction programme for nurses joining the team that provides for the documentation of training and the assessment of competency. However the document was not completed by the most recently appointed member of the nursing team during her induction. The nurse matron agreed that training and induction would be recorded according to protocol in future.

Executive recommendations for Licence Committee

All staff should be able to provide evidence of participation in mandatory health and safety training and BLS training (where appropriate) at the time of the next inspection.

Areas not covered on this inspection

Assessment of patients and donors Safe handling systems Recruitment and retention of staff

Evaluation
Some improvement required

Report compiled by:

Name…Debra Bloor…….

Designation……Inspector……..

Date…13 November 2006……

Appendix A: Centre Staff interviewed

James Hopkisson (PR) and six other members of the centres staff met with inspectors in the course of the inspection. Two patients also met with inspectors.

Appendix B: Licence history for previous 3 years

Licence	Type	Active From	Expires
L0076/11/a	Treatment with Storage	01/09/2005	28/02/2007
L0076/10/a	Treatment with Storage	01/03/2004	28/02/2007
L0076/9/a	Treatment with Storage	01/03/2001	29/02/2004

First licensed 1992

L0076/11/a, L0076/10/a

Conditions

- The centre should formalise the protocol detailing the procedure that is followed when a patient's GP does not respond to a request for information relating to the Welfare of the Child assessment or when concerns are raised.
- The centre should carry out an audit of consent forms held within patient records by the end of March 2004.

Recommendations

- Whilst acknowledging the centre's stance regarding the fitting of low-nitrogen level alarms to storage dewars, these should be fitted to all dewars used for the storage of patient material.

L0076/9/a

No conditions

Recommendations

- The patient information should be amended as follows:
  a) the patient information should be corrected in so far as it represents that the HFEA forbids any mixed ICSI/non-ICSI embryo transfers;
  b) the patient information should consistently state that a gamete or embryo donor can withdraw consent at any time up to the gamete or embryo being used in treatment;
  c) the consent form for donation of embryos to research should specify the particular research project that the embryo will be used in; and
  d) the OHSS information should be expanded and an emergency telephone number should be provided wherever OHSS is discussed in the patient information.

Appendix C:

RESPONSE OF PERSON RESPONSIBLE TO THE INSPECTION REPORT

Centre
Number……0076……

Name of PR……James Hopkisson……

Date of Inspection……18 October 2006……..

Date of Response……30 November 2006 ……

Please state any actions you have taken or are planning to take following the inspection with time scales

I have noted the recommendations made on Page 7. Specifically, we have set up a more robust document control system, in line with ISO requirements, that should prevent the problems with information review.

The embryology computer does now have a “time out” facility.
Dr Sjoblom has not completed her HPC registration because of maternity leave. This will be addressed upon her return in 2007.

The witnessing steps for sperm pots have now been implemented.

I have read the inspection report and agree to meet the requirements of the report.

Name…….James Hopkisson …….

Date……30 November 2006 ……